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PATENT  
P-5430P1

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT(S): AMISS et al.  
SERIAL NO.: 10/776,643 GROUP:  
FILING DATE: 02/12/2004 EXAMINER:  
FOR: BINDING PROTEINS AS BIOSENSORS

Mail Stop Amendments  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT  
(SUBMISSION AFTER FILING OF AN APPLICATION  
BUT BEFORE FINAL REJECTION OR NOTICE OF ALLOWANCE  
OR CONCURRENTLY WITH A RULE 53(d) CPA APPLICATION  
OR WITH A RULE 1.114 RCE APPLICATION)

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO/SB/08A(s), attached hereto.

II. COPIES (check at least one box)

- a. ☒ Submitted herewith is a legible copy of (i) each foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.
- b. ☐ Some or all of the documents listed on the PTO/SB/08A are not enclosed because they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned.

III. CONCISE EXPLANATION OF THE RELEVANCE  
(check at least one box)

a. ☒ **DOCUMENTS IN THE ENGLISH LANGUAGE**

The attached patents, publications, or other information in the English language do not require a statement of relevancy.

b. ☐ **DOCUMENTS NOT IN THE ENGLISH LANGUAGE**

A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

c. ☐ **ENGLISH LANGUAGE SEARCH REPORT**

An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(A)(3).

d. ☐ **OTHER**

The following additional information is provided for the Examiner's consideration.

FEES

IV. ☒ THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b):  
(check one box)

- a. ☐ within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required. (This section is not to be used with RCE's and CPA's).
- b. ☐ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.
- c. ☐ concurrently with the filing of a Continued Prosecution Application under 37 C.F.R. § 1.53(d) or concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.
- d. ☒ before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required.

In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge Deposit Account No. 02-1666 in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

V. ☐ THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c):  
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before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

- a. ☐ No statement; therefore, a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).  
or
- b. ☐ See the statement below. No fee is required.

VI. STATEMENT UNDER 37 C.F.R. § 1.97(e) (check only one box)

The undersigned hereby states that

- a. ☐ each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- b. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.
- c. ☐ Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

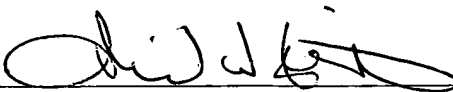
VII. PAYMENT OF FEES (check one box)

- ☐ A check in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p) is enclosed for the above-identified fee.
- ☐ Please charge Deposit Account No. 02-1666 in the amount required by 37 C.F.R. § 1.17(p) for the above-indicated fee. A triplicate copy of this paper is attached.
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If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-1666.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-1666 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Respectfully submitted,

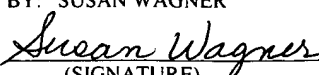
By   
David W. Highet, Reg. No. 30,265

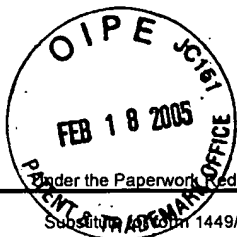
Date: February 16, 2005

Becton, Dickinson and Company  
1 Becton Drive, MC 089  
Franklin Lakes, New Jersey 07417  
(201) 847-6659

Enclosures: ☒ PTO/SB/08A  
☒ Documents  
☐ Foreign Search Report  
☐ Fee  
☐ Other:

Y:BDT Legal\P-5430P1

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER FOR PATENTS, MAIL STOP AMENDMENT, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 ON: FEBRUARY <u>16</u> , 2005	
BY: SUSAN WAGNER  (SIGNATURE)	<u>2/16/05</u> (DATE)



PTO/SB/08A (04-03)

Approved for use through 04/30/2003. OMB 0651-0031  
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Substituted Form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/776,643
Filing Date	12-Feb-2004
First Named Inventor	AMISS et al.
Art Unit	
Examiner Name	
Attorney Docket Number	P-5430P1

Sheet 1 of 6

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US- 5341805	08-30-1994	STAVRIDIS et al.	
		US- 5342789	08-30-1994	CHICK et al.	
		US- 5470714	11-28-1995	KLEINFELD.	
		US- 5517313	05-14-1996	COLVIN, Jr.	
		US- 5910661	06-08-1999	COLVIN, Jr.	
		US- 6197534	03-06-2001	LAKOWICZ et al.	
		US- 6277627	08-21-2001	HELLINGA.	
		US- 6521446	02-18-2003	HELLINGA	
		US- 2002004217A1	01-10-2002	HELLINGA	
		US- 2003130167A1	07-10-2003	PITNER et al.	
		US- 2003134346A1	07-17-2003	AMISS et al.	
		US- 2003153026A1	08-14-2003	ALARCON et al.	
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
		WO0003727A1	01-27-2000	LAKOWICZ ET AL.		
		WO9934212A1	07-08-1999	HELLINGA		
		WO9423284A1	10-13-1994	STAVRIDIS ET AL.		
		WO9109310A1	06-27-1991	KLEINFELD		

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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		Application Number	10/776,643
		Filing Date	12-Feb-2004
		First Named Inventor	AMISS et al.
		Art Unit	
		Examiner Name	
Sheet	2	of	6
		Attorney Docket Number	P-5430P1

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		BJORKMAN et al., Multiple Open Forms of Ribose-binding Protein Trace the Path of its Conformational Change. J. Mol. Biol. (1987) 279:651-64.	
		BOOS et al., Transport Properties of the Galactose-Binding Protein of Escherichia Coli: Occurrence of Two Conformational States. J. Biol. Chem. (1971) 246:621-28.	
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		BRUNE et al., Direct, Real-Time Measurement of Rapid Inorganic Phosphate Release Using a Novel Fluorescent Probe and Its Application to Actomyosin Subfragment 1 ATPase, Biochem. (1994) 33(27):8262-71.	
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		DRUECKHAMMER D. G., New Approaches to Fluorescence Based Glucose Sensors, Database FEDRIP on Dialog, N111S, 00313296, Identifying No. 1R21DK55234-01, Abstract (1998).	

Examiner Signature		Date Considered	
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Sheet	3	of	6
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		GE et al., Genetically Engineered Binding Proteins as Biosensors for Fermentation and Cell Culture. Biotech. Eng. (2003) 84:723.	
		GILARDI et al., Engineering the Maltose Binding Protein for Reagentless Fluorescence Sensing. Anal. Chem. (1994) 66:3840-47.	
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		LUCK et al., 19F NMR Studies of the D-Galactose Chemosensory Receptor. 1. Sugar Binding Yields a Global Structural Change. Biochem. (1991) 30:4248-56.	
		MARVIN et al., Engineering biosensors by introducing fluorescent allosteric signal transducers: Construction of a novel glucose sensor. J. Am. Chem. Soc., (1998) 120:7-11.	
		MARVIN et al., Manipulation of Ligand Binding Affinity by Exploitation of Conformational Coupling. Nature Structural Biology (2001) 8:795-98.	

Examiner Signature	Date Considered
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1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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Sheet	4	of	6	Attorney Docket Number	P-5430P1

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		MARVIN et al., The rational design of allosteric interactions in a monomeric protein and its applications to the construction of biosensors, Proc. Natl. Acad. Sci. (1997) 94:4366-71.	
		NEU et al., The release of enzymes from Escherichia coli by osmotic shock and during the formation of spheroplasts. Journal of Biological Chemistry, (1965) 240:3685-91.	
		PICKUP J., Developing glucose sensors for n vivo use, Trends in Biotech. (1993) 11:285-91.	
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		SALINS et al., A Novel Reagentless Sensing System for Measuring Glucose Based on the Galactose/Glucose-Binding Protein. Analytical Biochemistry 2001, 294:19-26.	
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		SCHULTZ et al., Affinity sensors for individual metabolites. Biotechnology and Bioengineering Symp. 9 (1979) 9:65-71.	
		SHILTON et al., Conformational Changes of Three Periplasmic Receptors for Bacterial Chemotaxis and Transport: The Maltose-, Glucose/Galactose- and Ribose-binding Proteins. J. Mol. Biol. (1996) 265:350-63.	

Examiner Signature	Date Considered
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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		TOLOSA et al., (1999). Glucose Sensor for Low-Cost Lifetime-Based Sensing Using a Genetically Engineered Protein. Anal. Biochem. (1999) 267:114.	
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		WILKINS et al., Glucose monitoring: state of the art and future possibilities, Med. Eng. Phys. (1996) 18(4):273-88.	
		ZHOU et al., Periplasmic Binding Protein Based Biosensors. 1. Preliminary Study of Maltose Binding Protein as Sensing Element for Maltose Biosensor. Biosensors; Bioelectronics (1991) 6:445-450.	
		ZUKIN et al., Effect of an Induced Conformational Change on the Physical Properties of Two Chemotactic Receptor Molecules." Biochemistry (1979) 18:5599-605.	

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Application Number 10/776,643

Filing Date 12-Feb-2004

First Named Inventor AMISS et al.

Art Unit

Examiner Name

Attorney Docket Number P-5430P1

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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		ZUKIN et al., Properties of the galactose binding protein of salmonella typhimurium and Escherichia coli. Biochemistry (1977) 16:381-86.	
		ZUKIN et al., Use Of A Distant Reporter Group As Evidence For A Conformational Change In A Sensory Receptor. Proc. Natl. Acad. Sci. (1977) 74:1932-36.	
		ZUKIN, R. S.; Evidence for a Conformational Change in the Escherichia Coli Maltose Receptor by Excited-State Fluorescence Lifetime Data. Biochemistry (1979) 18:2139-45.	

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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